

**UNITED STATES DEPARTMENT OF COMMERCE****United States Patent and Trademark Office**Address: COMMISSIONER OF PATENTS AND TRADEMARKS
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/962,040	10/31/97	CAVNEY	J

002292 HM42/0723 EXAMINER
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ART UNIT	PAPER NUMBER
	1614

DATE MAILED: 07/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No. 08/962,040	Applicant(s) Carney et al.
Examiner Dwayne C. Jones	Art Unit 1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on the Interview Summary of 13 JUL 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 17-51 is/are pending in the application.
- 4a) Of the above, claim(s) 17-27 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 28-51 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claims 17-27 are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) All b) Some* c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) Notice of References Cited (PTO-892) 18) Interview Summary (PTO-413) Paper No(s). 20
- 16) Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152)
- 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 20) Other: _____

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DETAILED ACTION

Status of Claims

1. Claims 17-51 are pending.
2. Claims 28-51 are elected and rejected.
3. Claims 17-27 are non-elected and withdrawn from consideration.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 28-51 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.
6. In this rejection is presumed that applicants intend to prevent or retard physiological aging and not chronological aging, since the latter reads on the stoppage of time, which is not credible on its face. The preventing or retarding of aging via systemic treatment is itself not credible on its face in view of contemporary knowledge in the art. No compound is currently known which would have these effects.

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7. Physiological aging is a multi-faceted process which does not involve a single chemical or biological effect. Various theories have been propounded (see Lehninger et al., pages 341, 344) including (1) loss of telomerase activity and the relationship of telomerase activity and the relationship of telomere length to cell death, (2) accumulation of DNA mutations, and (3) temporal genes which regulate the output of structural genes. In view of these theories, one skilled in the art would conclude that the diverse aspects of aging, e.g. loss of muscle tone, slowing of metabolism, greying of hair, etc. operate via different mechanisms. There is no reason why one skilled in the art would expect a single compound to prevent or retard all of these diverse aspects.

8. A systemic anti-aging utility has been alleged in U.S. Patent No. 5,157,031, but that utility is neither exemplified nor claimed therein. Furthermore, since the claims 28-51 are directed to methods, the utility is limited to those recited methods and there is no non-asserted well established utility for such methods.

Claim Rejections - 35 USC § 112

9. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 28-51 are rejected under 35 U.S.C. 112, first paragraph, since the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly

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connected, to make or use the invention. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The specification does not provide support or guidance to make or use trapping compounds to prevent or treat aging. Furthermore, the specification fails to provide support or guidance to treat a patient suffering from a dysfunction or a disease condition arising from oxidative damage, such as with Parkinson's disease, with derivatives of alpha-phenyl-N-phenylnitroline. Without such information, one skilled in the art could not predict which analogs or prodrugs out of the vast numbers of potential derivatives would react to treat, let alone prevent, the litany of diseases which are purported to be treated let alone prevented with the administration of alpha-phenyl-N-phenylnitroline. Accordingly, one skilled in the art would be required to perform undue experimentation to identify any *other* derivatives which could be used in conjunction with the spin trapping compounds to treat, let alone prevent, various disease resulting from oxidative damage. And so, one skilled in the art could not make or use the invention without undue experimentation.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to D. C. Jones whose telephone number is (703) 308-4634. The examiner can normally be reached on Mondays through Fridays from 8:30 am to 6:00 pm. The examiner can also be reached on alternate Mondays.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application or proceeding

should be directed to the receptionist whose telephone number is (703) 308-1235.

DWAYNE C. JONES
PRIMARY EXAMINER
Tech. Ctr. 1614
July 16, 2001